IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WARNER CHILCOTT COMPANY, LLC and WARNER CHILCOTT (US), LLC Plaintiffs, v. WATSON LABORATORIES, INC. – FLORIDA Defendant.	Civil Action No. 11-5989 (FSH/PS)
WARNER CHILCOTT COMPANY, LLC and WARNER CHILCOTT (US), LLC Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. Defendant.	Civil Action No. 11-6936 (FSH/PS)
WARNER CHILCOTT COMPANY, LLC and WARNER CHILCOTT (US), LLC Plaintiffs, v. RANBAXY, INC. and RANBAXY LABORATORIES LTD., Defendant.	Civil Action No. 12-cv-2474 (FSH/PS)

JOINT CLAIM CONSTRUCTION AND PREHEARING STATEMENT

Plaintiffs Warner Chilcott Company, LLC and Warner Chilcott (US), LLC (collectively, "Warner Chilcott") and Watson Laboratories, Inc. – Florida, Teva Pharmaceuticals USA, Inc., Ranbaxy, Inc. and Ranbaxy Laboratories Ltd. (collectively, "Defendants") hereby provide their Joint Claim Construction and Prehearing Statement concerning U.S. Patent Nos. 7,645,459 ("the '459 patent"), 7,645,460 ("the '460 patent") and 8,246,989 ("the '989 patent") in accordance with Local Patent Rule 4.3 of the United States District Court for the District of New Jersey and this Court's Ninth Amended Pretrial Scheduling Order of November 5, 2012.

I. BACKGROUND

This is a Hatch-Waxman Act patent infringement action. Warner Chilcott asserts, among other things, that Defendants have infringed the '459 patent, the '460 patent and the '989 patent by filing their Abbreviated New Drug Applications ("ANDA") with the U.S. Food and Drug Administration seeking approval to market generic versions of Warner Chilcott's Atelvia® product. Defendants allege, among other things, that the products proposed in their ANDAs will not infringe the asserted claims of the '459, '460 and '989 patents, and that those asserted claims are invalid.

II. CONSTRUCTION OF TERMS

A. Construction of Terms on Which the Parties Agree

Local Patent Rule 4.3(a) requires parties to identify the constructions of those terms on which the parties agree. The parties have not reached agreement on any of the terms identified in their Statements under Local Patent Rule 4.1(a).

B. Each Party's Proposed Construction of the Claim Terms in Dispute

In accordance with Local Patent Rule 4.3(b), the parties identify the following disputed terms from the asserted claims of the '459, '460 and '989 patents and propose the following constructions for those terms:

Patent and Claims	Disputed Claim Term	Warner Chilcott's Proposed Claim Construction	Defendants' Proposed Claim Construction	Impact of Proposed Construction on Merits of the Case
'459 patent, claims 1-16 and 21-22. '460 patent, claims 1-20 and 27-28.	"pharmaceutically effective absorption"[1]	An amount of a chelating compound high enough to significantly bind the metal ions and minerals in food but low enough not to significantly alter absorption of the bisphosphonate as compared to absorption in the fasted state. That is, absorption is similar with or without food. Given the high variability of bisphosphonate absorption, fed exposure within about 50% of fasting exposure is expected to be pharmaceutically effective absorption.	fed exposure of bisphosphonate within about 50% of fasting exposure	The parties agree that the construction of the disputed terms is material to questions of infringement and/or invalidity, but that no single disputed term or group of disputed terms appears to be more significant than any other.
'460	"a delayed release	A mechanism	one or more	

[1] Defendants assert that "pharmaceutically acceptable absorption" is a claim limitation. Warner Chilcott has advised Defendants that it will not dispute whether this phrase is a claim limitation in the '459 and '460 patents for purposes of claim construction.

Patent and Claims	Disputed Claim Term	Warner Chilcott's Proposed Claim Construction	Defendants' Proposed Claim Construction	Impact of Proposed Construction on Merits of the Case
patent, claims 1-7 and 10-14	mechanism to immediately release the risedronate"	designed to effect release of risedronate at some generally predictable location in the small intestine in an immediate release fashion.	excipients that will delay release of the bisphosphonate and chelating agent until the oral dosage form has reached the small intestine, and all of the bisphosphonate and chelating agent will be released from the oral dosage form within 60 minutes when measured by a standard USP method	
'460 patent, claims 8-9, 15-20 and 27-28	"an enteric coating which provides for immediate release"	A coating comprised of one or more polymers designed to dissolve in a pH dependent manner and which effects release of the contents of a core in an immediate release fashion as the coating dissolves. An enteric coating includes coatings that are insoluble at a pH below pH 5.5, but soluble between about pH 5.5 and about pH 6.5.	a pH-triggered coating that will delay release of the bisphosphonate and chelating agent until the oral dosage form has reached the small intestine, and all of the bisphosphonate and chelating agent will be released from the oral dosage form within 60 minutes when measured by a standard USP method	
'459 patent, claims 1-7	"a delayed release mechanism"	A mechanism designed to effect release at some generally predictable location	one or more excipients that will delay release of the bisphosphonate	

Patent and Claims	Disputed Claim Term	Warner Chilcott's Proposed Claim Construction	Defendants' Proposed Claim Construction	Impact of Proposed Construction on Merits of the Case
'989 patent, claims 1-9, 12, 14-22, 25 and 27 [2]		in the lower GI tract more distal to that which would have been accomplished without the mechanism.	and chelating agent until the oral dosage form has reached the lower GI tract	
'459 patent, claims 8-16 and 21-22	"an enteric coating which provides for release"	A coating comprised of one or more polymers designed to dissolve in a pH dependent manner and which effects release of the contents of a core. An enteric coating includes coatings that are insoluble at a pH below pH 5.5, but soluble at pH 5.5 or higher.	a pH-triggered coating that will delay release of the bisphosphonate and chelating agent until the oral dosage form has reached the small intestine	
'459 patent, claims 1-7 '460 patent, claims 1-7 and 10-14	"EDTA"	The chelating agent ethylenediamine tetraacetic acid and its salts.	ethylenediamine tetraacetic acid and its salts.	
'989 patent, claims 1-9, 12, 14-22, 25 and	"oral dosage form"	Any pharmaceutical composition intended to be administered to the lower gastrointestinal tract	a pharmaceutical composition containing a safe and effective amount of a chelating agent that	

[2] Defendant Watson Laboratories, Inc. - Florida does not consider this term/phrase to require construction.

Patent and Claims	Disputed Claim Term	Warner Chilcott's Proposed Claim Construction	Defendants' Proposed Claim Construction	Impact of Proposed Construction on Merits of the Case
27		of a human or other mammal via the mouth of said human or other mammal.	exhibits fed exposure of risedronate within about 50% of fasting exposure	
'989 patent, claims 1-9, 12, 14-22, 25 and 27 [2]	"EDTA or a pharmaceutically acceptable salt thereof"	The chelating agent ethylenediamine tetraacetic acid and salts acceptable for pharmaceuticals, such as disodium EDTA.	ethylenediamine tetraacetic acid and salts thereof suitable for use in a drug product	
'989 patent, claims 3-9, 12, and 14 [2]	"pH dependent enteric coating"	A coating material comprised of one or more polymers designed to dissolve in a pH dependent manner and which effects release of the contents of a core as the coating dissolves. An enteric coating includes coatings that are insoluble at a pH below pH 5.5, but soluble at pH 5.5 or higher.	a pH-triggered coating that will delay release of the bisphosphonate and chelating agent until the oral dosage form has reached the small intestine	
'989 patent, claims 15-22, 25 and 27 [2]	"pH dependent enteric coating of the granules"	The pH dependent enteric coating that contains the granules.	coating individual granules containing the risedronate and EDTA with a pH-triggered coating	

As required by Local Patent Rule 4.3(b), Exhibit A sets forth the parties' proposed constructions for each of these claim terms, and also identifies the intrinsic and

extrinsic evidence that each party intends to rely upon in support of its respective constructions or to oppose any other party's proposed construction.

C. Claim Terms Whose Construction Will Be Most Significant or Dispositive

Local Patent Rule 4.3(c) requires the parties to identify the constructions that will be most significant to the resolution of the case and whether any disputed terms will be case or claim dispositive, or substantially conducive to promoting settlement.

The parties do not believe that any single disputed term or group of disputed terms appears to be more significant than any other to the resolution of these cases, or that the construction of the disputed term(s) will be case or claim dispositive, or substantially conducive to promoting settlement.

D. Anticipated Length of Time Necessary for the Claim Construction Hearing

In accordance with Local Patent Rule 4.3(d), the parties estimate that the claim construction hearing will require no more than 4 hours (2 hours allocated to Warner Chilcott and 2 hours allocated to Defendants, collectively).

E. Identification of Witnesses for the Claim Construction Hearing

In accordance with Local Patent Rule 4.3(e), no party intends to call any witnesses at the claim construction hearing.

Respectfully submitted,

By its attorneys for Plaintiffs:

Date: November 12, 2012

s/ William J. O'Shaughnessy

William J. O'Shaughnessy
Jonathan M.H. Short
MCCARTER & ENGLISH LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
Telephone: (973) 622-4444
Facsimile: (973) 624-7070

OF COUNSEL:
Dominick A. Conde (*pro hac vice*)
Steven C. Kline (*pro hac vice*)
Gregory B. Sephton (*pro hac vice*)
Chandrika Vira (*pro hac vice*)
Charlotte Jacobsen (*pro hac vice*)
Joshua A. Davis (*pro hac vice*)
FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104
Telephone: (212) 218-2100
Facsimile: (212) 218-2200

Attorneys for Plaintiffs
Warner Chilcott Company, LLC
and Warner Chilcott (US), LLC

By their attorneys for Defendants:

Date: November 12, 2012

s/ Arnold B. Calmann

Arnold B. Calmann
Geri Albin
SAIBER LLC
One Gateway Center
10th Floor
Newark, New Jersey 07102
(973) 622-3333
(973) 622-3349 (facsimile)

OF COUNSEL:
B. Jefferson Boggs
Matthew L. Fedowitz
MERCHANT & GOULD PC
1701 Duke Street, Suite 310
Alexandria, Virginia 22314
(703) 684-2500
(793) 684-2501 (facsimile)

Christopher J. Sorenson
Aaron M. Johnson
MERCHANT & GOULD PC
3200 IDS Center
80 S. Eighth Street
Minneapolis, Minnesota 55402
(612) 332-5300
(612) 332-9018 (facsimile)

Attorneys for Defendant
Watson Laboratories, Inc. – Florida.

s/ Michael E. Patunas

Michael E. Patunas
Mayra V. Tarantino
LITE DEPALMA GREENBERG, LLC
Two Gateway Center
12th Floor
Newark, New Jersey 07102
(973) 622-3000
(973) 877-3872 (facsimile)

OF COUNSEL:
Elizabeth J. Holland
Robert V. Cerwinski
Lee B. Shelton
Matthew C. Ruedy
Linnea P. Cipriano
KENYON & KENYON LLP
One Broadway
New York, New York 10004-1050
(212) 425-7200
(212) 425-5288 (facsimile)

Attorneys for Defendant
Teva Pharmaceuticals USA, Inc.

s/ Sheila Raftery Wiggins

Sheila Raftery Wiggins
DUANE MORRIS LLP
One Riverfront Plaza
1037 Raymond Boulevard
Suite 1800
Newark, New Jersey 07102
(973) 424-2055
(973) 556-1486 (facsimile)

Matthew C. Mousley
DUANE MORRIS LLP
30 S. 17th St.
Philadelphia, PA 19103
(215) 979-1804
(215) 689-4936 (facsimile)

Anthony J. Fitzpatrick
Vincent L. Capuano
Carolyn A. Alenci
DUANE MORRIS LLP
Suite 2400
100 High Street
Boston, MA 02110
(857) 488-4200
(857) 488-4201 (facsimile)

Attorneys for Defendants Ranbaxy, Inc. and Ranbaxy Laboratories Limited.

EXHIBIT A

The Parties' Proposed Constructions and Evidence Regarding the Claim Terms

Claim Term	Warner Chilcott's Proposed Claim Construction and Evidence	Defendants' Proposed Claim Construction and Evidence
"pharmaceutically effective absorption" [3] (`459 patent and '460 patent)	***Proposed Construction*** An amount of a chelating compound high enough to significantly bind the metal ions and minerals in food but low enough not to significantly alter absorption of the bisphosphonate as compared to absorption in the fasted state. That is, absorption is similar with or without food. Given the high variability of bisphosphonate absorption, fed exposure within about 50% of fasting exposure is expected to be pharmaceutically effective absorption. ***Intrinsic Evidence*** U.S. Patent No. 7,645,459 (" '459 patent") and prosecution history, including without limitation: '459 patent, col. 4, 11. 59-67. U.S. Patent No. 7,645,460 (" '460 patent") and prosecution history, including without limitation:	Defendants believe that the phrase "having pharmaceutically effective absorption" should be construed as being a claim limitation. ***Proposed Construction*** fed exposure of bisphosphonate within about 50% of fasting exposure ***Intrinsic Evidence*** The specifications, claims and file histories of the '459 and '460 patents, including but not limited to the following: '459 patent, col. 4, ll. 59–67 (WTS0005519–5545 including WTS0005522). U.S. Patent Application 11/106,816 ("'816 application"), p. 6, ll. 25–30 (WTS0005566–5626 including WTS0005575).

[3] Defendants assert that "pharmaceutically acceptable absorption" is a claim limitation. Warner Chilcott has advised Defendants that it will not dispute whether this phrase is a claim limitation in the '459 and '460 patents for purposes of claim construction.

Claim Term	Warner Chilcott's Proposed Claim Construction and Evidence	Defendants' Proposed Claim Construction and Evidence
	'460 patent, col. 4, 1. 64 — col. 5, 1. 5. ***Extrinsic Evidence*** Expert testimony: Plaintiffs may rely on expert testimony[4] as to the person of ordinary skill in the art at the time of the invention and to explain the ordinary meaning of "pharmaceutically acceptable absorption" as it would be understood by a person of ordinary skill in the art or to describe or elucidate "pharmaceutically acceptable absorption."	'460 patent, col. 4, l. 64–col. 5, l. 5 (WTS0005546–5564 including WTS0005549–5550). U.S. Patent Application 11/286,875 ("'875 application"), p. 6, ll. 30–35 (WTS0006851–6890 including WTS0006860). '459 Patent Prosecution History, Amendment dated June 1, 2009 (WTS0006702–6716 including WTS0006708, WTS0006709, WTS0006712, WTS0006715). '459 and '460 Patent Prosecution Histories, David E. Burgio, Ph.D. Declaration Under 37 C.F.R. §§ 1.68 and 1.1.32 (WTS0006745–6768 including WTS0006754–6755, WTS0006757–6758, WTS0006760–6761; WTS0007473–7496 including WTS0007482–7483, WTS0007485–7486, WTS0007488–7489). '460 Patent Prosecution History, Amendment dated June 1, 2009 (WTS0007497–7509 including WTS0007497, WTS0007500, WTS0007502). '881 application, p. 1, ll. 17–20, p. 4, ll. 5–8

[4] Warner Chilcott has indicated that it intends to present expert opinion only in rebuttal to any offered by Defendants in their opening claim construction papers. Defendants object to Warner Chilcott's failure to specifically identify the witnesses on whom it may rely for rebuttal expert testimony. Warner Chilcott has explained that until it knows what, if any, expert testimony Defendants submit affirmatively, it is not in position to identify what experts it will use in rebuttal, but states that it has previously identified Dr. Bob Davis as a potential expert.

Claim Term	Warner Chilcott's Proposed Claim Construction and Evidence	Defendants' Proposed Claim Construction and Evidence
		(WTS0007586–7626 including WTS0007588, WTS0007591). ***Extrinsic Evidence*** *Approved Drug Products*, (23d ed., Food and Drug Administration 2003), pp. viii, x (TEV0012432–12435 including TEV0012433, TEV0012435). *Guidance for Industry: Bioavailability and Bioequivalence Studies for Orally Administered Drug Products – General Considerations* (2003), pp. 3, 6, 8, 20 (TEV0012341–0012366 including TEV0012346, TEV0012349, TEV0012351, TEV0012363). *Guidance for Industry: Food-Effect Bioavailability and Fed Bioequivalence Studies* (December 2002), pp. 6-8 (RAN-RIS-00007612–7623 including RAN-RIS00007620–7622). Defendants may rely on declarations/testimony from Dr. Edmund Elder and/or Dr. John Yates concerning the state of the art at the time the purported invention was made, the person of ordinary skill in the art, and the meaning of the term "pharmaceutically effective absorption" to a person of ordinary skill in the art, including without limitation that the term would have the meaning that Defendants have proposed to one of ordinary skill in the art. Drs. Elder and/or Yates may also explain the principles, technology and terminology underlying their opinions, and may use

Claim Term	Warner Chilcott's Proposed Claim Construction and Evidence	Defendants' Proposed Claim Construction and Evidence
		demonstrative aids and exhibits to explain their opinions.
"a delayed release mechanism to immediately release the risedronate" ('460 patent)	***Proposed Construction*** A mechanism designed to effect release of risedronate at some generally predictable location in the small intestine in an immediate release fashion. ***Intrinsic Evidence*** '460 patent and prosecution history, including without limitation: '460 patent, col. 4, 11. 31-35; col. 7, 11. 61-67; col. 8, 11. 49-54. ***Extrinsic Evidence*** Expert testimony: Plaintiffs may rely on expert testimony as to the person of ordinary skill in the art at the time of the invention and to explain the ordinary meaning of "a delayed release mechanism to immediately release the risedronate" as it would be understood by a person of ordinary skill in the art or to describe or elucidate "a delayed release mechanism to immediately release the risedronate."	***Proposed Construction*** one or more excipients that will delay release of the bisphosphonate and chelating agent until the oral dosage form has reached the small intestine, and all of the bisphosphonate and chelating agent will be released from the oral dosage form within 60 minutes when measured by a standard USP method ***Intrinsic Evidence*** The specifications, claims and file histories of the '459 and '460 patents, including but not limited to the following: '460 patent, col. 4, ll. 14–24, col. 4, ll. 31–35, col. 5, ll. 24–35, col. 11, l. 44–col. 12, l. 31 (WTS0005546–5564 including WTS0005549–5550, WTS0005553). '875 application, p. 5, ll. 27–34, p. 6, ll. 7–10, p. 7, ll. 17–24, p. 17, l. 8–p.18, l. 25 (WTS0006851–6890 including WTS0006859–6861, WTS0006871–6872). '459 patent, col. 5, ll. 25–37, col. 9, ll. 50–55, col. 10, ll. 17–25, col. 17, l. 28–col. 18, l. 22 (WTS0005519–5545 including WTS0005523, WTS0005525, 5529). '816 application, p. 7, ll. 16–24, p. 13, l. 36–p. 14, l. 8, p. 14, ll. 28–33, p. 25, l. 25–p. 27, l. 9 (WTS0005566–

Claim Term	Warner Chilcott's Proposed Claim Construction and Evidence	Defendants' Proposed Claim Construction and Evidence
		5626 including WTS0005576, 5582–5583, WTS0005594–5595). '881 application, p. 5, l. 33–p. 6, l. 7, p. 10, ll. 18–21, p. 10, l. 37–p. 11, l. 8, p. 19, l. 6–p. 20, l. 12 (WTS0007586–7626 including WTS0007592–7593, WTS0007597–7598, WTS0007606–7607). ***Extrinsic Evidence*** 1980 USP, Dissolution, pp. 959–960. (TEV0013846–TEV0013849). 2003 USP, Drug Release, pp. 2157–2165. (TEV0013850–TEV0013860). 2009 Second USP Supplement, Risedronate Sodium Tablets, pp. 4279–4281. (TEV0013841–TEV0013845). Defendants may rely on declarations/testimony from Dr. Edmund Elder and/or Dr. John Yates concerning the state of the art at the time the purported invention was made, the person of ordinary skill in the art, and the meaning of the term "a delayed release mechanism to immediately release" to a person of ordinary skill in the art, including without limitation that the term would have the meaning that Defendants have proposed to one of ordinary skill in the art. Drs. Elder and/or Yates may also explain the principles, technology and terminology underlying their opinions, and may use

Claim Term	Warner Chilcott's Proposed Claim Construction and Evidence	Defendants' Proposed Claim Construction and Evidence
		demonstrative aids and exhibits to explain their opinions.
"an enteric coating which provides for immediate release" ('460 patent)	***Proposed Construction*** A coating comprised of one or more polymers designed to dissolve in a pH dependent manner and which effects release of the contents of a core in an immediate release fashion as the coating dissolves. An enteric coating includes coatings that are insoluble at a pH below pH 5.5, but soluble between about pH 5.5 and about pH 6.5. ***Intrinsic Evidence*** '460 patent and prosecution history, including without limitation: '460 patent, col. 7, 11. 61-67; col. 9, 11. 39-49. ***Extrinsic Evidence*** Expert testimony: Plaintiffs may rely on expert testimony as to the person of ordinary skill in the art at the time of the invention and to explain the ordinary meaning of "an enteric coating which provides for immediate release" as it would be understood by a person of ordinary skill in the art or to describe or elucidate "an enteric coating which provides for immediate release."	***Proposed Construction*** a pH-triggered coating that will delay release of the bisphosphonate and chelating agent until the oral dosage form has reached the small intestine, and all of the bisphosphonate and chelating agent will be released from the oral dosage form within 60 minutes when measured by a standard USP method ***Intrinsic Evidence*** The specifications, claims and file histories of the '459 and '460 patents, including but not limited to the following: '460 patent, col. 4, ll. 14–24, col. 9, ll. 45–49 (WTS0005546–5564 including WTS0005549, WTS0005552); *See generally* '460 patent: col. 8, l. 63–col. 9, l. 44; col. 9, l. 54–col. 11, l. 42 (WTS0005546–5564 including WTS0005551–5553). '875 application, p. 5, ll. 27–34, p. 14, ll. 7–10 (WTS0006851–6890 including WTS0006859, WTS0006868); *See generally* '875 application: p. 12, l. 35–p. 14, l. 6; p. 14, l. 14–p. 17, l. 6. (WTS0006851–6890 including WTS0006866–6871). '459 patent, col. 11, ll. 59–63 (WTS0005519–5545 including WTS0005526); *See generally* '459 patent: col. 9, l. 55–col. 10, l. 16; col. 10, l. 26–col. 11, l. 58;

Claim Term	Warner Chilcott's Proposed Claim Construction and Evidence	Defendants' Proposed Claim Construction and Evidence
		col. 12, l. 1–col. 17, l. 26. (WTS0005525–5529). '881 application, 12, ll. 31–33(WTS0007586–7626 including WTS0007599); *See generally* '881 application: p. 10, ll. 21–36; p. 11, l. 8–p. 12, l. 30; p. 12, l. 37–p. 18, l. 39. (WTS0007586–7626 including WTS0007597–7605). '816 application, p. 17, ll. 14-17 (WTS0005566–5626 including WTS0005586); *See generally* '816 application: p. 14, l. 7–p. 14, l. 27; p. 14, l. 34–p. 17, l. 13; p. 17, l. 21–p. 25, l. 23. (WTS0005566–5626 including WTS0005583–5594). ***Extrinsic Evidence*** 1980 USP, Dissolution, pp. 959–960. (TEV0013846–TEV0013849). 2003 USP, Drug Release, pp. 2157–2165. (TEV0013850–TEV0013860). 2009 Second USP Supplement, Risedronate Sodium Tablets, pp. 4279–4281. (TEV0013841–TEV0013845). Defendants may rely on declarations/testimony from Dr. Edmund Elder and/or Dr. John Yates concerning the state of the art at the time the purported invention was made, the person of ordinary skill in the art, and the meaning of the term "an enteric coating which

Claim Term	Warner Chilcott's Proposed Claim Construction and Evidence	Defendants' Proposed Claim Construction and Evidence
		provides for immediate release" to a person of ordinary skill in the art, including without limitation that the term would have the meaning that Defendants have proposed to one of ordinary skill in the art. Drs. Elder and/or Yates may also explain the principles, technology and terminology underlying their opinions, and may use demonstrative aids and exhibits to explain their opinions.
"a delayed release mechanism" ('459 patent)	***Proposed Construction*** A mechanism designed to effect release at some generally predictable location in the lower GI tract more distal to that which would have been accomplished without the mechanism. ***Intrinsic Evidence*** '459 patent and prosecution history, including without limitation: '459 patent, col. 10, 11. 17-25. ***Extrinsic Evidence*** Expert testimony: Plaintiffs may rely on expert testimony as to the person of ordinary skill in the art at the time of the invention and to explain the ordinary meaning of "delayed release mechanism" as it would be understood by a person of ordinary skill in the art or to describe or elucidate "delayed release mechanism."	***Proposed Construction*** one or more excipients that will delay release of the bisphosphonate and chelating agent until the oral dosage form has reached the lower GI tract ***Intrinsic Evidence*** The specifications, claims and file histories of the '459 and '460 patents, including but not limited to the following: '459 patent, col. 5, ll. 25–37, col. 9, ll. 50–55, col. 10, ll. 17–25, col. 17, l. 28–col. 18, l. 22 (WTS0005519–5545 including WTS0005523, WTS0005525, WTS0005529); '816 application, p. 7, ll. 16–24, p. 13, l. 36–p. 14, l. 8, p. 14, ll. 28–33, p. 25, l. 25–p. 27, l. 9 (WTS0005566–5626 including WTS0005576, WTS0005582–5583, WTS0005594–WTS0005595). '881 application, p. 5, l. 33–p. 6, l. 7, p. 10, ll. 18–21, p.

Claim Term	Warner Chilcott's Proposed Claim Construction and Evidence	Defendants' Proposed Claim Construction and Evidence
		10, l. 37–p. 11, l. 8, p. 19, l. 6–p. 20, l. 12 (WTS0007586–7626 including WTS0007592–7593, WTS0007597–7598, WTS0007606–7607). '460 patent, col. 4, ll. 31–35, col. 5, ll. 24–35, col. 11, l. 44–col. 12, l. 31 (WTS0005546–5564 including WTS0005549–5550, WTS0005553). '875 application, p. 6, ll. 7–10, p. 7, ll. 17–24, p. 17, l. 8–p.18, l. 25 (WTS0006851–6890 including WTS0006860–6861, WTS0006871–WTS006872). ***Extrinsic Evidence*** Defendants may rely on declarations/testimony from Dr. Edmund Elder and/or Dr. John Yates concerning the state of the art at the time the purported invention was made, the person of ordinary skill in the art, and the meaning of the term "delayed release mechanism" to a person of ordinary skill in the art, including without limitation that the term would have the meaning that Defendants have proposed to one of ordinary skill in the art. Drs. Elder and/or Yates may also explain the principles, technology and terminology underlying their opinions, and may use demonstrative aids and exhibits to explain their opinions.
"an enteric coating which provides for release" ('459 patent)	***Proposed Construction*** A coating comprised of one or more polymers designed to dissolve in a pH dependent manner and which effects release of the contents of a core. An	***Proposed Construction*** a pH-triggered coating that will delay release of the bisphosphonate and chelating agent until the oral dosage form has reached the small intestine

Claim Term	Warner Chilcott's Proposed Claim Construction and Evidence	Defendants' Proposed Claim Construction and Evidence
	enteric coating includes coatings that are insoluble at a pH below pH 5.5, but soluble at pH 5.5 or higher. ***Intrinsic Evidence*** '459 patent and prosecution history, including without limitation: '459 patent, col. 11, 11. 51-63. ***Extrinsic Evidence*** Expert testimony: Plaintiffs may rely on expert testimony as to the person of ordinary skill in the art at the time of the invention and to explain the ordinary meaning of "an enteric coating which provides for release" as it would be understood by a person of ordinary skill in the art or to describe or elucidate "an enteric coating which provides for release."	***Intrinsic Evidence*** The specifications, claims and file histories of the '459 and '460 patents, including but not limited to the following: '459 patent, col. 9, ll. 50–55, col. 11, ll. 59–63 (WTS0005519–5545 including WTS0005525–5526); *See generally* '459 patent: col. 9, l. 55–col. 10, l. 16; col. 10, l. 26–col. 11, l. 58; col. 12, l. 1–col. 17, l. 26. (WTS0005519–5545 including WTS0005525–5529). '816 application, p. 13, l. 37–p. 14, l. 8, p. 17, l. 14–17 (WTS0005566–5626 including WTS0005582–5583, WTS0005586). *See generally* '816 application: p. 14, l. 7–p. 14, l. 27; p. 14, l. 34–p. 25, l. 23. (WTS0005566–5626 including WTS0005583–5594). '881 application, p. 10, ll. 18–21, p. 12, ll. 31–33 (WTS0007586–7626 including WTS0007597, WTS0007599). *See generally* '881 application: p. 10, l. 21–36; p. 11, l. 8–p. 12, l. 30; p. 12, l. 37–p. 18, l. 39. (WTS0007586–7626 including WTS0007597–7605). ***Extrinsic Evidence*** Defendants may rely on declarations/testimony from Dr. Edmund Elder and/or Dr. John Yates concerning the state of the art at the time the purported invention was made, the person of ordinary skill in the art, and

Claim Term	Warner Chilcott's Proposed Claim Construction and Evidence	Defendants' Proposed Claim Construction and Evidence
		the meaning of the term "an enteric coating which provides for release" to a person of ordinary skill in the art, including without limitation that the term would have the meaning that Defendants have proposed to one of ordinary skill in the art. Drs. Elder and/or Yates may also explain the principles, technology and terminology underlying their opinions, and may use demonstrative aids and exhibits to explain their opinions.
"EDTA" ('459 patent and '460 patent)	***Proposed Construction*** The chelating agent ethylenediamine tetraacetic acid and its salts. ***Intrinsic Evidence*** '459 patent and prosecution history, including without limitation: '459 patent, col. 2, 11. 37-38; col. 7, 11. 36-41; col. 8, 1. 33. Examiner's Amendment / Reasons for Allowance dated 10/20/2009 in application no. 11/106,816 (WTS0006790-96 at WTS0006795). '460 patent and prosecution history, including without limitation: '460 patent, col. 2, 11. 37-38; col. 6, 11. 45-51.	***Proposed Construction*** ethylenediamine tetraacetic acid and its salts. ***Intrinsic Evidence*** The specifications, claims and file histories of the '459 and '460 patents, including but not limited to the following: Claims 1–7, of the '459 patent; Claims 1–7, 10–14 of the '460 patent. '459 patent, col. 7, ll. 36–40, col. 8, ll. 27–33, col. 8, ll. 62–66, col. 8, ll. 66–67, col. 9, ll. 38–41 (WTS0005519–5545 including WTS0005524–5525); '816 application, p. 10, ll. 22–25, p. 11, ll. 32–36, p. 12, ll. 25–27, p. 12, ll. 27–29, p. 13, ll. 26–28 (WTS0005566–5626 including WTS0005579–5582); '460 patent, col. 6, ll. 46–50, col. 8, ll. 14–17, col. 7, ll.

Claim Term	Warner Chilcott's Proposed Claim Construction and Evidence	Defendants' Proposed Claim Construction and Evidence
	Examiner's Amendment / Reasons for Allowance dated 10/20/2009 in application no. 11/286,875 (WTS0007530-35 at WTS0007533). ***Extrinsic Evidence*** Expert testimony: Plaintiffs may rely on expert testimony as to the person of ordinary skill in the art at the time of the invention and to explain the ordinary meaning of "EDTA" as it would be understood by a person of ordinary skill in the art or to describe or elucidate "EDTA."	30–34, col. 7, ll. 35–36 (WTS0005546–5564 including WTS0005550–5551); '875 application, p. 9, ll. 16–19, p. 10, ll. 21–23, p. 10, ll. 23–25, p. 11, ll. 26–28 (WTS0006851–6890 including WTS0006863–6865). '881 application, p. 8, ll. 21–23, p. 8, ll. 32–36, p. 9, ll. 21–22, p. 9, ll. 18–20 (WTS0007586–7626 including WTS0007595–7596). '459 Patent Prosecution History, Preliminary Amendment, May 13, 2008 (WTS0006169–6176 including WTS0006175). '459 Patent Prosecution History, Interview Summary, October 20, 2009 (WTS0006790–6792 including WTS0006791). '459 Patent Prosecution History, Supplemental Notice of Allowability, October 20, 2009 (WTS0006793–6796 including WTS0006795). '460 Patent Prosecution History, Preliminary Amendment, May 13, 2008 (WTS0006932–6940 including WTS0006939). '460 Patent Prosecution History, Interview Summary, October 20, 2009 (WTS0007528). '460 Patent Prosecution History, Supplemental Notice

Claim Term	Warner Chilcott's Proposed Claim Construction and Evidence	Defendants' Proposed Claim Construction and Evidence
		of Allowability, October 20, 2009 (WTS0007530–7535 including WTS0007533). ***Extrinsic Evidence*** Kibbe, A.H., Editor, *Handbook of Pharmaceutical Excipients*, Third Edition, Pharmaceutical Press and American Pharmaceutical Association, London, GB and Washington, DC (2000) (TEV0011967–11972). Whittaker, P., et al., Toxicological Profile, *Current Use, and Regulatory Issues on EDTA Compounds for Assessing Use of Sodium Iron EDTA for Food Fortification, Regulatory Toxicology and Pharmacology*, 18:419-427 (December 1993) (WTS0007883–7891). Lachman, *Antioxidants and Chelating Agents as Stabilizers in Liquid Dosage Forms*, The Indian Journal of Pharmacy. 30: 109-119 (1968) (TEV0012217–12229 including TEV0012225). 10/08/2009 Supplemental Notice of Allowability (Examiner Interview Summary), U.S. Patent Application 12/183,359 ("'359 application") (TEV0013819). 10/08/2009 Supplemental Notice of Allowability (Reasons for Allowance), '359 application. (TEV0013820–TEV0013823 including TEV0013822).

Claim Term	Warner Chilcott's Proposed Claim Construction and Evidence	Defendants' Proposed Claim Construction and Evidence
		10/08/2009 Supplemental Notice of Allowability (Examiner Interview Summary), U.S. Patent Application 12/183,336 ("'336 application") (TEV0013246–TEV0013252 including TEV0013247). 10/08/2009 Supplemental Notice of Allowability (Reasons for Allowance), '336 application. (TEV0013246–TEV0013252 including TEV0013250). Defendants may rely on a declaration/testimony from Dr. Edmund Elder concerning the state of the art at the time the purported invention was made, the person of ordinary skill in the art, and the meaning of the term "EDTA" to a person of ordinary skill in the art, including without limitation that the term would have the meaning that Defendants have proposed to one of ordinary skill in the art. Dr. Elder may also explain the principles, technology and terminology underlying his opinions, and may use demonstrative aids and exhibits to explain his opinions.
"oral dosage form" ('989 patent)	***Proposed Construction*** Any pharmaceutical composition intended to be administered to the lower gastrointestinal tract of a human or other mammal via the mouth of said human or other mammal. ***Intrinsic Evidence*** '989 patent and prosecution history, including without limitation:	***Proposed Construction*** a pharmaceutical composition containing a safe and effective amount of a chelating agent that exhibits fed exposure of risedronate within about 50% of fasting exposure ***Intrinsic Evidence*** The specifications, claims and file histories of the '459, '460, and '989 patents, including but not limited to the

Claim Term	Warner Chilcott's Proposed Claim Construction and Evidence	Defendants' Proposed Claim Construction and Evidence
	'989 patent, col. 5, ll. 4-16. ***Extrinsic Evidence*** Expert testimony: Plaintiffs may rely on expert testimony as to the person of ordinary skill in the art at the time of the invention and to explain the ordinary meaning of "oral dosage form" as it would be understood by a person of ordinary skill in the art or to describe or elucidate "oral dosage form."	following: '989 patent, col. 1, ll. 15–27, col. 3, ll. 17–31; col. 3, ll. 45–59, col. 4, ll. 34–43, col. 4, l. 62–col. 5, l. 16, col. 9, ll. 30–36, col. 37, ll. 1–14. '989 Prosecution History, Notice of Allowance, September 4, 2012 (WTS0010588–10594 at 10593). U.S. Patent Application 12/637,100 ("'100 application"), ¶ 2, ¶ 11-12, ¶ 21, ¶ 24, ¶ 25, ¶ 47, ¶ 233–34 (WTS0009967–10028). U.S. Patent Application 11/106,816 ("'816 application"), p. 1, ll. 12–23, p. 4, ll. 10–20, p. 4, l. 29–p. 5, l. 8, p. 6, ll. 5–11, p. 6, l. 25–p. 7, l. 7, p. 13, ll. 19–23, p. 55, l. 19–p. 56, l. 6 (WTS0005566–5626). '459 patent, col. 1, ll. 12–24, col. 3, ll. 14–28; col. 3, ll. 42–56, col. 4, ll. 31–40, col. 4, l. 59–col. 5, l. 13, col. 9, ll. 28–34, col. 37, ll. 30–40 (WTS0005519–5545). '460 patent, col. 1, ll. 13–24, col. 3, ll. 14–27, col. 3, ll. 40–54, col. 4, ll. 41–49, col. 4, l. 64–col. 5, l. 12, col. 8, ll. 4–10 (WTS0005546–5564). U.S. Patent Application 11/286,875 ("'875 application"), p. 1, ll. 13–20, p. 4, ll. 10–19, p. 4, l. 28–p. 5, l. 8, p. 6, ll. 14–19, p. 6, ll. 30–35, p. 7, ll. 5–9, p. 11, ll. 19–23 (WTS0006851–6890).

Claim Term	Warner Chilcott's Proposed Claim Construction and Evidence	Defendants' Proposed Claim Construction and Evidence
		'459 Patent Prosecution History, Amendment dated June 1, 2009 (WTS0006702–6716 including WTS0006708, WTS0006709, WTS0006712–6715). '459 and '460 Patent Prosecution Histories, David E. Burgio, Ph.D. Declaration Under 37 C.F.R. §§ 1.68 and 1.1.32 (WTS0006745–6768 including WTS0006754–6755, WTS0006757–6758, WTS0006760–6761; WTS0007473–7496 including WTS0007482–7483, WTS0007485–7486, WTS0007488–7489). '460 Patent Prosecution History, Amendment dated June 1, 2009 (WTS0007497–7509 including WTS0007497, WTS0007500–7503). '881 application, p. 1, ll. 13–20, p. 3, l. 16–18, p. 3, l. 32–p. 4, l. 8, p. 4, ll. 31–36, p. 5, ll. 18–25, p. 10, ll. 5–6, p. 32, ll. 9–21, p. 34, ll. 21–22 (WTS0007586–7626). ***Extrinsic Evidence*** *Approved Drug Products*, (23d ed., Food and Drug Administration 2003), pp. viii, x (TEV0012432–12435 including TEV0012433, TEV0012435). *Guidance for Industry: Bioavailability and Bioequivalence Studies for Orally Administered Drug Products – General Considerations* (2003), pp. 3, 6, 8, 20 (TEV0012341–0012366 including TEV0012346, TEV0012349, TEV0012351,

Claim Term	Warner Chilcott's Proposed Claim Construction and Evidence	Defendants' Proposed Claim Construction and Evidence
		TEV0012363). *Guidance for Industry: Food-Effect Bioavailability and Fed Bioequivalence Studies* (December 2002), pp. 6–8 (RAN-RIS-00007612–7623 including RAN-RIS-00007620–7622). Defendants may rely on declarations/testimony from Dr. Edmund Elder and/or Dr. John Yates concerning the state of the art at the time the purported invention was made, the person of ordinary skill in the art, and the meaning of the term "oral dosage form" to a person of ordinary skill in the art, including without limitation that the term would have the meaning that Defendants have proposed to one of ordinary skill in the art. Drs. Elder and/or Yates may also explain the principles, technology and terminology underlying their opinions, and may use demonstrative aids and exhibits to explain their opinions.
"EDTA or a pharmaceutically acceptable salt thereof"[5] ('989 patent)	***Proposed Construction*** The chelating agent ethylenediamine tetraacetic acid and salts acceptable for pharmaceuticals, such as disodium EDTA. ***Intrinsic Evidence*** '989 patent and prosecution history, including without	***Proposed Construction*** ethylenediamine tetraacetic acid and salts thereof suitable for use in a drug product ***Intrinsic Evidence*** The specifications, claims and file histories of the '459, '460, and '989 patents, including but not limited to the

[5] Defendant Watson Laboratories, Inc. - Florida does not consider this term/phrase to require construction.

Claim Term	Warner Chilcott's Proposed Claim Construction and Evidence	Defendants' Proposed Claim Construction and Evidence
	limitation: '989 patent, col. 2, ll. 40-41; col. 7, ll. 38-43; col. 8, l. 35; col. 9, ll. 40-41. ***Extrinsic Evidence*** Expert testimony: Plaintiffs may rely on expert testimony as to the person of ordinary skill in the art at the time of the invention and to explain the ordinary meaning of "EDTA or a pharmaceutically acceptable salt thereof" as it would be understood by a person of ordinary skill in the art or to describe or elucidate "EDTA or a pharmaceutically acceptable salt thereof."	following: Claims 1–27 of the '989 patent; Claims 1–7, of the '459 patent; Claims 1–7, 10–14 of the '460 patent. '989 patent, col. 7, ll. 37–43, col. 8, ll. 29–35, col. 8, l. 64–col. 9, l. 2, col. 9, ll. 40–43 (WTS0009943–9965). '100 application, ¶ 38, ¶43, ¶ 44, ¶ 47 (WTS0009967–10028). '459 patent, col. 7, ll. 36–40, col. 8, ll. 27–33, col. 8, ll. 62–67, col. 9, ll. 38–41 (WTS0005519–5545 including WTS0005524–5525). '816 application, p. 10, ll. 22–25, p. 11, ll. 32–36, p. 12, ll. 25–27, p. 12, ll. 27–29, p. 13, ll. 26–28 (WTS0005566–5626 including WTS0005579–5582). '460 patent, col. 6, ll. 46–50, col. 8, ll. 14–17, col. 7, ll. 30–34, col. 7, ll. 35–36 (WTS0005546–5564 including WTS0005550–5551). '875 application, p. 9, ll. 16–19, p. 10, ll. 21–23, p. 10, ll. 23–25, p. 11, ll. 26–28 (WTS0006851–6890 including WTS0006863–6865). '881 application, pg. 8, ll. 21–23, pg. 8, ll. 32–36, p. 9, ll. 21–22, p. 9, ll. 18–20 (WTS0007586–7626 including WTS0007595–7596).

Claim Term	Warner Chilcott's Proposed Claim Construction and Evidence	Defendants' Proposed Claim Construction and Evidence
		'459 Patent Prosecution History, Preliminary Amendment, May 13, 2008 (WTS0006169–6176 including WTS0006175). '459 Patent Prosecution History, Interview Summary, October 20, 2009 (WTS0006790–6792 including WTS0006791). '459 Patent Prosecution History, Supplemental Notice of Allowability, October 20, 2009 (WTS0006793–6796 including WTS0006795). '460 Patent Prosecution History, Preliminary Amendment, May 13, 2008 (WTS0006932–6940 including WTS0006939). '460 Patent Prosecution History, Interview Summary, October 20, 2009 (WTS0007528). '460 Patent Prosecution History, Supplemental Notice of Allowability, October 20, 2009 (WTS0007530–7535 including WTS0007533). ***Extrinsic Evidence*** Arthur H. Kibbe, *Handbook of Pharmaceutical Excipients*, 191-94 (Arthur H. Kibbe ed., Pharmaceutical Press & Am. Pharmaceutical Ass'n 2000) (1986) (TEV0011967–11972). Whittaker, P., et al., *Toxicological Profile, Current*

Claim Term	Warner Chilcott's Proposed Claim Construction and Evidence	Defendants' Proposed Claim Construction and Evidence
		Use, and Regulatory Issues on EDTA Compounds for Assessing Use of Sodium Iron EDTA for Food Fortification, Regulatory Toxicology and Pharmacology, 18:419–427 (December 1993) (WTS0007883–7891). Lachman, *Antioxidants and Chelating Agents as Stabilizers in Liquid Dosage Forms*, The Indian Journal of Pharmacy. 30: 109–119 (1968) (TEV0012217–12229 including TEV0012225). 10/08/2009 Supplemental Notice of Allowability (Examiner Interview Summary), U.S. Patent Application 12/183,359 ("'359 application") (TEV0013819). 10/08/2009 Supplemental Notice of Allowability (Reasons for Allowance), '359 application. (TEV0013820–TEV0013823 including TEV0013822). 10/08/2009 Supplemental Notice of Allowability (Examiner Interview Summary), U.S. Patent Application 12/183,336 ("'336 application") (TEV0013246–TEV0013252 including TEV0013247). 10/08/2009 Supplemental Notice of Allowability (Reasons for Allowance), '336 application. (TEV0013246–TEV0013252 including TEV0013250).

Claim Term	Warner Chilcott's Proposed Claim Construction and Evidence	Defendants' Proposed Claim Construction and Evidence
		Defendants may rely on declarations/testimony from Dr. Edmund Elder concerning the state of the art at the time the purported invention was made, the person of ordinary skill in the art, and the meaning of the term "EDTA or a pharmaceutically acceptable salt thereof" to a person of ordinary skill in the art, including without limitation that the term would have the meaning that Defendants have proposed to one of ordinary skill in the art. Dr. Elder may also explain the principles, technology and terminology underlying his opinions, and may use demonstrative aids and exhibits to explain his opinions.
"a delayed release mechanism" [5] ('989 patent)	***Proposed Construction*** A mechanism designed to effect release at some generally predictable location in the lower GI tract more distal to that which would have been accomplished without the mechanism. ***Intrinsic Evidence*** '989 patent and prosecution history, including without limitation: '989 patent, col. 10, ll. 18-26. ***Extrinsic Evidence*** Expert testimony: Plaintiffs may rely on expert	***Proposed Construction*** one or more excipients that will delay release of the bisphosphonate and chelating agent until the oral dosage form has reached the lower GI tract ***Intrinsic Evidence*** The specifications, claims and file histories of the '459, '460, and '989 patents, including but not limited to the following: '989 patent, col. 5, ll. 28–40, col. 9, ll. 51–56, col. 10, ll. 18–26, col. 17, l. 31–col. 18, l. 5. (WTS0009943–9965). '100 application, ¶ 27-29, ¶ 48, ¶ 49, ¶ 90-98

Claim Term	Warner Chilcott's Proposed Claim Construction and Evidence	Defendants' Proposed Claim Construction and Evidence
	testimony as to the person of ordinary skill in the art at the time of the invention and to explain the ordinary meaning of "a delayed release mechanism" as it would be understood by a person of ordinary skill in the art or to describe or elucidate "a delayed release mechanism."	(WTS0009967–10028). '459 patent, col. 5, ll. 25–37, col. 9, ll. 50–55, col. 10, ll. 17–25, col. 17, l. 28–col. 18, l. 22 (WTS0005519–5545 including WTS0005523, WTS0005525, WTS0005529). '816 application, p. 7, ll. 15–24, p. 13, l. 36–p. 14, l. 8, p. 14, ll. 28–33, p. 25, l. 25–p. 27, l. 9 (WTS0005566–5626 including WTS0005576, WTS0005582–5583, WTS0005594–WTS0005595). '881 application, p. 5, l. 33–p. 6, l. 7, p. 10, ll. 18–21, p. 10, l. 37–pg. 11, l. 8, p. 19, l. 6–p. 20, l. 12 (WTS0007586–7626 including WTS0007592–7593, WTS0007597–7598, WTS0007606–7607). '460 patent, col. 4, ll. 31–35, col. 5, ll. 24–35, col. 11, l. 44–col. 12, l. 38 (WTS0005546–5564 including WTS0005549–5550, WTS0005553). '875 application, p. 6, ll. 7–10, p. 7, ll. 17–24, p. 17, l. 8–p.18, l. 25 (WTS0006851–6890 including WTS0006860–6861, WTS0006871–WTS006872). ***Extrinsic Evidence*** Defendants may rely on declarations/testimony from Dr. Edmund Elder and/or Dr. John Yates concerning the state of the art at the time the purported invention was made, the person of ordinary skill in the art, and

Claim Term	Warner Chilcott's Proposed Claim Construction and Evidence	Defendants' Proposed Claim Construction and Evidence
		the meaning of the term "delayed release mechanism" to a person of ordinary skill in the art, including without limitation that the term would have the meaning that Defendants have proposed to one of ordinary skill in the art. Drs. Elder and/or Yates may also explain the principles, technology and terminology underlying their opinions, and may use demonstrative aids and exhibits to explain their opinions.
"pH dependent enteric coating" [5] ('989 patent)	***Proposed Construction*** A coating material comprised of one or more polymers designed to dissolve in a pH dependent manner and which effects release of the contents of a core as the coating dissolves. An enteric coating includes coatings that are insoluble at a pH below pH 5.5, but soluble at pH 5.5 or higher. ***Intrinsic Evidence*** '989 patent and prosecution history, including without limitation: '989 patent, col. 10, l. 62 - col. 11, l. 7; col. 11, ll. 53-65; col. 12, ll. 3-60. ***Extrinsic Evidence*** Expert testimony: Plaintiffs may rely on expert testimony as to the person of ordinary skill in the art	***Proposed Construction*** a pH-triggered coating that will delay release of the bisphosphonate and chelating agent until the oral dosage form has reached the small intestine ***Intrinsic Evidence*** The specifications, claims and file histories of the '459, '460, and '989 patents, including but not limited to the following: '989 patent, col. 9, ll. 51–56, col. 11, l. 61–col. 12, l. 2 (WTS0009943–9965); *See generally* '989 patent, col. 9, l. 56–col. 10, l. 17, col. 10, l. 27–col. 11, l. 60, col. 12, l. 3–col. 18, l. 5 (WTS0009943–9965). '100 application, ¶ 48, ¶ 60 (WTS0009967–10028) *See generally* '100 application, ¶ 50–59, ¶ 61–89 (WTS0009967–10028).

Claim Term	Warner Chilcott's Proposed Claim Construction and Evidence	Defendants' Proposed Claim Construction and Evidence
	at the time of the invention and to explain the ordinary meaning of "pH dependent enteric coating" as it would be understood by a person of ordinary skill in the art or to describe or elucidate "pH dependent enteric coating."	'459 patent, col. 9, ll. 50–55, col. 11, ll. 59–67 (WTS0005519–5545 including WTS0005525–5526); *See generally* '459 patent: col. 9, l. 55–col. 10, l. 16; col. 10, l. 26–col. 11, l. 58; col. 12, l. 1–col. 17, l. 26. (WTS0005519–5545 including WTS0005525–5529). '816 application, p. 13, l. 37–p. 14, l. 8, p. 17, ll. 14–17 (WTS0005566–5626 including WTS0005582–5583, WTS0005586); *See generally* '816 application: p. 14, ll. 7–27; p. 14, l. 34–p. 26, l. 24. (WTS0005566–5626 including WTS0005583–5594). '881 application, p. 10, ll. 18–21, p. 12, ll. 31–36 (WTS0007586–7626 including WTS0007597, WTS0007599); *See generally* '881 application: p. 10, ll. 21–36; p. 11, l. 8–p. 12, l. 30; p. 12, l. 37–p. 19, l. 32. (WTS0007586–7626 including WTS0007597–7605). ***Extrinsic Evidence*** Defendants may rely on declarations/testimony from Dr. Edmund Elder and/or Dr. John Yates concerning the state of the art at the time the purported invention was made, the person of ordinary skill in the art, and the meaning of the term "pH dependent enteric coating" to a person of ordinary skill in the art, including without limitation that the term would have the meaning that Defendants have proposed to one of ordinary skill in the art. Drs. Elder and/or Yates may also explain the principles, technology and terminology underlying their opinions, and may use

Claim Term	Warner Chilcott's Proposed Claim Construction and Evidence	Defendants' Proposed Claim Construction and Evidence
		demonstrative aids and exhibits to explain their opinions.
"pH dependent enteric coating of the granules" [5] ('989 patent)	***Proposed Construction*** The pH dependent enteric coating that contains the granules. ***Intrinsic Evidence*** '989 patent and prosecution history, including without limitation: '989 patent, col. 5, ll. 7-16; col. 10, l. 62 - col. 11, l. 7; col. 11, ll. 53-61. ***Extrinsic Evidence*** Expert testimony: Plaintiffs may rely on expert testimony as to the person of ordinary skill in the art at the time of the invention and to explain the ordinary meaning of "pH dependent enteric coating of the granules" as it would be understood by a person of ordinary skill in the art or to describe or elucidate "pH dependent enteric coating of the granules."	***Proposed Construction*** coating individual granules containing the risedronate and EDTA with a pH-triggered coating ***Intrinsic Evidence*** The specifications, claims and file histories of the '459, '460, and '989 patents, including but not limited to the following: '989 patent, col. 10, l. 61–col. 12, l. 23, col. 13, ll. 7–13, col. 14, l. 1–col. 15, l. 36 (WTS0009943– 9965). *See generally* '989 patent, col. 10, l. 61–col. 17, l. 30 (WTS0009943 – 9965). '100 application, ¶ 54–62, ¶ 67, ¶ 71–80 (WTS0009967–10028). *See generally* '100 application, ¶ 54–89 (WTS0009967–10028). '459 patent, col. 10, l. 60–col. 12, l. 21, col. 13, ll. 5–11, col. 13, l. 64–col. 15, l. 32 (WTS0005519–5545). *See generally* '459 patent, col. 10, l. 60–col. 17, l. 26 (WTS0005519–5545). '816 application, p. 15, l. 26–p. 17, l. 34; p. 19, ll. 7–12, p. 20, l. 17–p. 22, l. 27 (WTS0005566–5626). *See generally* '816 application, p. 15, l. 26–p. 25, l. 23

Claim Term	Warner Chilcott's Proposed Claim Construction and Evidence	Defendants' Proposed Claim Construction and Evidence
		(WTS0005566–5626). '460 patent, col. 9, l. 1–col. 10, l. 6 (WTS0005546–5564). See generally '460 patent, col. 9, l. 1–col. 11, l. 42 (WTS0005546–5564). '875 application, p. 13, l. 7–p. 14, l. 27 (WTS0006851–6890). See generally '875 application, p. 13, l. 7–p. 17, l. 6 (WTS0006851–6890). '881 application, p. 11, l. 19–p. 13, l. 15, p. 14, ll. 12–16, p. 14, l. 38–p. 16, l. 36 (WTS0007586–7626). *See generally* '881 application, p. 11, l. 19–p. 18, l. 39 (WTS0007586–7626). ***Extrinsic Evidence*** Defendants may rely on declarations/testimony from Dr. Edmund Elder concerning the state of the art at the time the purported invention was made, the person of ordinary skill in the art, and the meaning of the term "pH dependent enteric coating of the granules" to a person of ordinary skill in the art, including without limitation that the term would have the meaning that Defendants have proposed to one of ordinary skill in the art. Dr. Elder may also explain the principles, technology and terminology underlying his opinions, and may use demonstrative aids and exhibits to explain his opinions.